REMARKS

Applicant respectfully requests reconsideration.

Claims 1, 2, 4-21, 23-25, 42 and 86-99 were previously pending in this application.

Claims 8 and 92 are cancelled without prejudice or disclaimer.

Claims 1, 2, 7, 9-11, 14-16, 20, 21, 25, 42, 86-92, 94-97 and 99 are amended.

As a result, claims 1, 2, 4-7, 9-21, 23-25, 42 and 86-91 and 93-99 are pending for examination with claims 1, 2, 21 and 86 being independent claims.

No new matter has been added.

Rejections under 35 U.S.C. §112

New matter:

Claims 1, 4-11, 14-18, 20, 21, 23-25, 42 and 98 remain rejected under 35 U.S.C. §112, first paragraph, as containing new matter.

Claims 1 and 21 are amended herewith to recite compositions that comprise "an isolated β-1,6-glucosamine polymer." Support for these amendments can be found at least in originally filed claims 1 and 21.

Claim 25 is amended herewith to recite that the carrier compound is a protein. Support for this amendment can be found in the specification at least on page 18 line 10.

Reconsideration and withdrawal of this rejection is respectfully requested.

Written Description:

Claims 20, 42, 97 and 99 are rejected under 35 U.S.C. §112, first paragraph, written description.

Claims 20 and 97 recite compositions comprising an isolated polymer or an isolated polysaccharide that is formulated as a vaccine. Claims 42 and 99 recite compositions of claim 1 that comprise isolated polymer that stimulates an immune response against bacteria that make native PNAG. The Examiner asserts that these claims lack written description because Applicant did not have possession of the subject matter of these claims. Applicant respectfully traverses.

To provide an adequate written description, the "specification 'must clearly allow persons of ordinary skill in the art to recognize [the inventor] invented what is claimed.'" Gentry Gallery,

Inc. v. Berkline Corp., 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998) (internal citations omitted). The written description requirement for a claimed genus may be satisfied by description of a representative number of species by an actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Regents of Univ. of Calif. V. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The disclosure of only one or two species can support a genus claim. Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366-67, 79 U.S.P.Q.2d 1001, 1007-09 (Fed. Cir. 2006).

Applicant has disclosed the relevant, identifying characteristics of the claimed genus and has demonstrated that such characteristics correlate with the functional characteristics of the claimed genus. The rejected claims commonly recite an isolated β-1,6-glucosamine polymer, optionally conjugated to a carrier compound, that has less than 40% of its glucosamine amino groups substituted with acetate. The specification has identified that such a "deacetylated" version of PNAG is "highly immunogenic in vivo and preferentially elicits antibodies that mediate opsonic killing and protection from infection." (See page 2 lines 24-27.) The specification teaches the structure of the isolated polymer, whether or not conjugated to a carrier compound. (See page 3 line 6 through to page 5 line 21.)

The specification further teaches that pharmaceutical compositions are provided "which may be used as vaccines" and that "these compositions comprise the polysaccharide in an amount effective to stimulate an immune response, such as an antigen-specific immune response." (See page 6 lines 1-7.) Applicant notes that the definition of "vaccine" proffered by the Examiner is based, in part, on a definition of the term provided by the patent applicant in In re Wright and, as such, is not particularly relevant to the instant claims. In re Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993) ("Wright defines "vaccine" at page 1 of his specification as being a material which induces an organism to acquire immunity against disease.").

Notwithstanding this, however, Applicant has demonstrated that administration of the claimed isolated polysaccharide results in the production of opsonic antibodies that are able to kill Staphylococcal strains more efficiently than antibodies produced following administration of

highly acetylated forms of the claimed polysaccharide. See Example 6 and Figs. 5-9. As shown in Figs. 5-8, the polyclonal serum raised against dPNAG was more efficient, at every dilution tested, at killing bacteria than was the polyclonal serum raised against PNAG. One of ordinary skill in the art would reasonably conclude that the production of such opsonic antibodies within subjects receiving the claimed polymer or polysaccharide would lead to immunity in said subjects against bacteria that express PNAG.

In addition, these data clearly show that the claimed deacetylated polysaccharides are more efficient than the highly acetylated polysaccharides at inducing higher titers of opsonic antibodies specific for PNAG. Applicant has therefore clearly disclosed the structural feature that distinguishes the claimed polymers and polysaccharides from other polymers and polysaccharides and that correlates with the functional activity ascribed to the claimed polymers and polysaccharides. The Examiner is therefore incorrect when she states that the "as-filed specification fails to correlate the structure ... with requisite functions ...".

The Examiner has acknowledged that the working examples clearly show that isolated polymers or polysaccharides having 15-20% acetylation are capable of inducing opsonic antibodies. The Examiner, however, confuses "possession" with working examples. The written description requirement does not require the existence of working examples. Ariad Pharma, Inc. v. Eli Lilly & Co., No. 2008-1248, 2010 WL 1007369, at *13 (Fed. Cir. Mar. 22, 2010) ("We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement."). The specification provides the structural features that define the claimed genus and establishes that these features correlate with the functional activity of the genus. This disclosure, coupled with the instant working examples, leads one of ordinary skill in the art to reasonably conclude that Applicant invented what is being claimed (i.e., that Applicant has possession of the claimed invention).

The Examiner asserts that there is unpredictability relating to the solubility, immunogenicity, and immunospecific protective capacity of the claimed polymers and polysaccharides. However, the Examiner provides no basis or support for this position. This is merely unfounded Examiner argument.

The Examiner further cites Maira-Litran et al. (Infect. Immun. 73: 6752-6762, 2005) as showing that "the only staphylococcal dPNAG that was known to induce the most effective specific staphylococcal killing … was the one having 15% acetate substitution." The teaching within Maira-Litran et al. that certain species are the most effective at bacterial killing does not establish unpredictability with relation to the claimed genus. The most effective species, according to the report of Maira-Litran, is embraced by the instant claims. The Examiner has provided no evidence that other species within the claimed genus are not efficacious.

Moreover, Maira-Litran et al. further confirms the teachings and working examples of the instant specification. For example, the reference teaches that "The protection assays also supported the conclusion that antibodies reactive with the nonacetylated, backbone portion of the PNAG antigen were able to mediate clearance of bacteria from the blood and protection against a high-dose lethal infection" (see page 6760, left column, second full paragraph), and that "poorly acetylated forms of the vaccine are clearly capable of inducing the desired antibody" (see page 6761, left column, first paragraph).

In view of the foregoing, reconsideration and withdrawal of this rejection is respectfully requested.

Indefiniteness:

Claims 21, 23-25, 42 and 86-97 are rejected under 35 U.S.C. §112, second paragraph, for being indefinite.

Claim 42 is amended herewith to recite the full terminology for PNAG. Support for this amendment can be found on in the specification at least on page 2 lines 24-25. The claim is definite.

Claims 21, 86 and 87 are amended herewith to recite "an isolated β-1,6-glucosamine polymer conjugated to a carrier compound" or "an isolated polysaccharide conjugated to a carrier compound." The claims are definite.

Claims 23 and 24 have not been amended as proposed by the Examiner since such amendment does not find antecedent basis in claim 21 from which both claims depend. Claims 23 and 24 recite a new subgroup which has no antecedent basis in claim 21 and therefore there is no need to recite "the" as proffered by the Examiner. The claims are definite.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 86, 88, 92-95 and 97 are rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 7,157,443 (Joyce et al.).

Claim 86 is amended herewith to recite that less than 40% of the glucosamine amino groups are substituted with acetate. Joyce et al. report an antigen (SEA) having 40-60% of R_1 groups as H and the remainder of R_1 groups being $COCH_3$. Accordingly, the antigen of Joyce et al. may comprise 40-60% of R_1 groups that are $COCH_3$. Joyce et al. does not report an antigen having less than 40% of its glucosamine amino groups substituted with acetate. Joyce et al. therefore does not anticipate the rejected claims as now amended.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 2, 12, 13, 21, 23-25, 86-95 and 97 are rejected under 35 U.S.C. §102 as being anticipated by Yang et al. (Tetrahedron Lett., 2002, 43:7561-3).

Claims 2, 21 and 86 are amended herewith to recite that the isolated β-1,6-glucosamine polymer, optionally conjugated to a carrier compound, has a molecular weight of at least 1200 Daltons. Support for this amendment can be found at least in originally filed claim 9. Yang et al. does not teach a polymer or polysaccharide that is at least 1200 Daltons in molecular weight. Yang et al. therefore does not anticipate the rejected claims as now amended.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §103

Claim 19 is rejected under 35 U.S.C. §103(a) as being unpatentable over US 7,157,443 (Joyce et al.) as applied to claim 2 above.

Claim 19 depends from claim 2 which recites an isolated β-1,6-glucosamine polymer having less than 40% of glucosamine amino groups substituted with acetate. Claim 2 was not rejected in view of Joyce et al. Nevertheless, as discussed above, Joyce et al. report an antigen (SEA) that may comprise 40-60% of R_1 groups that are $COCH_3$. Joyce et al. does not report an antigen having less than 40% of its glucosamine amino groups substituted with acetate, nor does Joyce et al. suggest using a variant having less than 40% acetylation. Therefore one of ordinary

skill in the art would not have been motivated to make, and would not have had a reasonable expectation of success relating to, a polysaccharide antigen having less than 40% acetylation, as recited in claim 19, based on the teachings of Joyce et al. Claim 19 is not rendered obvious by Joyce et al. for at least these reasons.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 19 and 96 are rejected under 35 U.S.C. §103(a) as being unpatentable over Yang et al. (Tetrahedron Lett., 2002, 43:7561-3) as applied to claims 2 and 86 above.

Claims 19 and 96 depend respectively from claims 2 and 86 which recite either an isolated polymer or an isolated polysaccharide having a molecular weight of at least 1200 Daltons. Yang et al. does not report such a polymer or polysaccharide, nor does Yang et al. suggest using such a polymer or polysaccharide. Therefore one of ordinary skill in the art would not have been motivated to make, and would not have had a reasonable expectation of success relating to, a polymer or polysaccharide having a molecular weight of at least 1200 Daltons, as recited in claims 19 and 96, based on the teachings of Yang et al. Claims 19 and 96 are not rendered obvious by Yang et al. for at least these reasons.

Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. B0801.70255US01.

Respectfully submitted,

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